

REMARKS

I. STATUS OF THE CLAIMS

This Amendment and Response (the "Amendment") is submitted in response to the final Office Action dated February 3, 2009 (the "Office Action"). Claims 111-170 are rejected in the Office Action. Claims 111-138 are in independent form.

By this Amendment, as outlined above, Applicants have amended claims 111-138 to recite, *inter alia*, that the stent includes an open lattice tubular sidewall having an outer surface and an inner surface and a coating applied to at least a portion of the outer surface of the open lattice tubular sidewall, where the coating comprises an undercoat that covers at least a portion of the outer surface of the open lattice tubular sidewall, and a topcoat that at least partially covers the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall. In addition, by this Amendment, Applicants have added (a) claims 171, 173, 175 and 177, which recite that the stent of claims 111, 114, 128 and 131, respectively, is prefabricated, and (b) claims 172, 174, 176 and 178, which recite that the undercoat of claims 111, 114, 128 and 131, respectively, is in direct contact with the outer surface of the open lattice tubular sidewall.

All amendments are fully supported by the originally-filed specification and/or drawings of the present application. Examples of where support can be found in the specification are: page 13, lines 8-13; page 17, lines 9-32; page 23, lines 23-33; and Figure 9. It is believed that no new matter has been added. Applicants expressly reserve the right to pursue the subject matter of any previously presented claims in one or more continuation applications.

Following entry of this Amendment, claims 111-178 remain pending in the application.

II. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

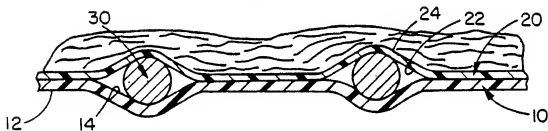
In paragraph 5 of the Office Action, claims 111, 124, 125, 139-141, 154, 155, 169 and 170 are rejected under 35 U.S.C. § 102(b) ("Section 102(b)") as allegedly being anticipated by U.S. Patent No. 5,123,917 to Lee (hereinafter "Lee"). The rejection is traversed for at least the following reasons.

Independent claims 111, 124 and 125 are directed to stents having an open lattice tubular sidewall comprising a metal and having an outer surface and an inner surface where at least a portion of the outer surface of the open lattice tubular sidewall is covered with a coating. The

coating comprises (1) an undercoat comprising a hydrophobic elastomeric material, and (2) a topcoat comprising a second polymer material that is different from the hydrophobic elastomeric material. At least a portion of the undercoat covers at least a portion of the outer surface of the open lattice tubular sidewall. The topcoat at least partially covers the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall. Accordingly, both the undercoat and topcoat of the coating are disposed on the outer surface of the open lattice tubular sidewall. Applicants respectfully submit that Lee fails to disclose or suggest stents having such a coating.

More specifically, Lee teaches that its graft comprises ring-like scaffold members 30 that are positioned *between* a cylindrical inner layer or tube 10 and a cylindrical outer layer or tube 20.” (Lee, col. 5, lines 16-17; *see also* col. 2, lines 34-42; col. 3, lines 58-63). Figure 4 of Lee, which is a greatly enlarged cross-sectional view of a portion of Figure 3 and is reproduced below, shows that the inner layer 10 is disposed on the inner surface of the ring-like scaffold members 30 and the outer layer 20 is disposed on the outer surface of the ring-like scaffold members 30.

FIG. 4



Thus, in Lee's graft, the inner layer 10 and the outer layer 20 are not both disposed on the outer surface of the scaffold members 30. In contrast, in the presently claimed stents, both the undercoat and topcoat of the coating are disposed on the outer surface of the open lattice tubular sidewall. Therefore, Lee fails to disclose or suggest a stent having an open lattice tubular sidewall and a coating, which comprises an undercoat and a topcoat, in which (1) the undercoat comprises a first polymer and covers at least a portion of the outer surface of the open lattice tubular sidewall and (2) the topcoat comprises a second polymer, different from the first

polymer, and covers at least a portion of the undercoat that covers the outer surface of the open lattice tubular sidewall.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *M.P.E.P.* § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed Cir. 1987)). Accordingly, because Lee fails to disclose each and every element set forth in the claims, the Section 102(b) rejection must fail as a matter of law. Therefore, Applicants respectfully submit that independent claims 111, 124 and 125 are not anticipated by Lee and request that the Section 102 rejections be withdrawn.

For at least the foregoing reasons, it is believed that independent claims 111, 124 and 125, and their respective dependent claims 139-141, 154, 155, 169 and 170, are patentable over Lee.

III. THE REJECTIONS UNDER 35 U.S.C. § 103(a)

A. The Claims Are Patentable Over Lee in View of Berg

In paragraph 9 of the Office Action, claims 112, 113, 129, 130, 142, 143, 159 and 160 are rejected under 35 U.S.C § 103(a) (“Section 103(a)”) as allegedly being unpatentable over Lee in view of U.S. Patent No. 5,464,650 to Berg *et al.* (hereinafter “Berg”).

Independent claims 112, 113, 129 and 130 are directed to stents having an open lattice tubular sidewall stent structure comprising stainless steel and having an outer surface and an inner surface where at least a portion of the outer surface of the open lattice tubular sidewall is covered with a coating for release of a biologically active material. The coating comprises (1) an undercoat comprising an ethylene vinyl acetate copolymer material incorporating an amount of a biologically active material, and (2) a topcoat comprising a biostable polymeric material, which is different from the ethylene vinyl acetate copolymer material. At least a portion of the undercoat covers at least a portion of the outer surface of the open lattice tubular sidewall. The topcoat covers at least a portion of the undercoat that covers the outer surface of the open lattice tubular sidewall. Applicants respectfully submit that Lee and Berg, taken alone or in combination, fail to disclose or suggest stents having such a coating.

As discussed above in Section II, Lee fails to disclose or suggest a stent having an open lattice tubular sidewall and a coating, which comprises an undercoat and a topcoat, in which (1) the undercoat comprises a first polymer and covers at least a portion of the outer surface of the open lattice tubular sidewall and (2) the topcoat comprises a second polymer, different from the first polymer, and covers the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall. Applicants respectfully submit that Berg fails to cure the deficiencies of Lee.

In particular, Berg discloses that compositions containing the same polymer are applied to its stent. Berg does not disclose or even suggest a coating having an undercoat comprising a first polymer, and a topcoat that comprises a second polymer that this different from the first polymer. Further, none of the stents prepared in Berg's examples include a plurality of layers having different polymers. Each example only discloses the use of a single polymer to form the coatings. (*See Berg*, col. 5, line 45 to col. 7, line 15). Therefore, Berg also fails to disclose or suggest a stent having a coating, which comprises an undercoat and a topcoat, in which (1) the undercoat comprises a first polymer and covers at least a portion of the outer surface of the open lattice tubular sidewall of the stent and (2) the topcoat comprises a second polymer, different from the first polymer, and covers the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall of the stent.

For at least the foregoing reasons, Applicants respectfully submit that independent claims 112, 113, 129 and 130, and their respective dependent claims 139, 140, 142, 143, 159, 160, 169 and 170, are patentable over Lee and Berg, either taken alone or in combination. Accordingly, Applicants respectfully request that the rejection based on Lee and Berg be withdrawn.

B. The Claims Are Patentable Over Lee in view of Berg and Mitchell

In addition, in paragraph 11 of the Office Action, claims 114-116, 118-121, 128, 131-138, 144-146, 148-151, 158 and 161-168 are rejected under Section 103(a) as allegedly being unpatentable over Lee in view of Berg, and further in view of U.S. Patent No. 5,288,711 to Mitchell *et al.* (hereinafter "Mitchell").

Independent claims 114-116, 118-121, 128 and 131-138 are directed to stents having an open lattice tubular sidewall stent structure comprising a metal or stainless steel and having an outer surface and an inner surface. At least a portion of the outer surface of the open lattice

tubular sidewall is covered with a coating for release of a biologically active material. The coating comprises (1) an undercoat comprising an ethylene vinyl acetate copolymer material incorporating an amount of a biologically active material, and (2) a topcoat comprising a biostable polymeric material, which is different from the ethylene vinyl acetate copolymer material. At least a portion of the undercoat covers at least a portion of the outer surface of the open lattice tubular sidewall. The topcoat covers at least a portion of the undercoat that covers the outer surface of the open lattice tubular sidewall. Applicants respectfully submit that Lee, Berg and Mitchell, taken alone or in combination, fail to disclose or suggest stents having such a coating.

As discussed above, Lee and Berg fail to disclose or suggest a stent having a coating, which comprises an undercoat and a topcoat, in which (1) the undercoat comprises a first polymer and covers at least a portion of the outer surface of the open lattice tubular sidewall of the stent and (2) the topcoat comprises a second polymer, different from the first polymer, and covers the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall of the stent. Mitchell also fails to disclose or suggest such a stent. In fact, Mitchell does not disclose or suggest any coated stent.

For at least the foregoing reasons, Applicants respectfully submit that independent claims 114-116, 118-121, 128 and 131-138, and their respective dependent claims 139, 140, 144-146, 148-151, 158 and 161-170, are patentable over Lee, Berg and Mitchell, either taken alone or in combination. Accordingly, Applicants respectfully request that the rejection based on Lee, Berg and Mitchell be withdrawn.

C. The Claims Are Patentable Over Lee in view of Mitchell

In paragraph 13 of the Office Action, claims 117, 122, 123, 126, 127, 147, 152, 153, 156 and 157 are rejected under Section 103(a) as allegedly being unpatentable over Lee in view of Mitchell.

Independent claims 117, 122, 123, 126 and 127 are directed to stents having an open lattice tubular sidewall stent structure comprising a metal and having an outer surface and an inner surface where at least a portion of the outer surface of the open lattice tubular sidewall is covered with a coating. The coating comprises (1) an undercoat comprising a hydrophobic elastomeric material, and (2) a topcoat comprising a second polymer material that is different

from the hydrophobic elastomeric material. At least a portion of the undercoat covers at least a portion of the outer surface of the open lattice tubular sidewall. The topcoat covers the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall. Applicants respectfully submit that Lee and Mitchell, taken alone or in combination, fail to disclose or suggest the stents of these claims.

As discussed above, Lee and Mitchell fail to disclose or suggest a stent having an open lattice tubular sidewall and a coating, which comprises an undercoat and a topcoat, in which (1) the undercoat comprises a first polymer and covers at least a portion of the outer surface of the open lattice tubular sidewall and (2) the topcoat comprises a second polymer, different from the first polymer, and covers the portion of the undercoat that covers the outer surface of the open lattice tubular sidewall. Therefore, Applicants respectfully submit that Lee and Mitchell, either alone or in combination, fail to disclose or suggest the claimed stent.

For at least the foregoing reasons, it is believed that independent claims 117, 122, 123, 126 and 127, and their respective dependent claims 139, 140, 147, 152, 153, 156, 157, 169 and 170, are patentable over Lee and Mitchell, either taken alone or in combination. Accordingly, Applicants respectfully request that the rejection based on Lee and Mitchell be withdrawn.

IV. THE NEW CLAIMS

New claims 171, 173, 175 and 177 depend on independent claims 111, 114, 128 and 131, respectively, and new claims 172, 174, 176, and 178 depend on independent claims 111, 114, 128 and 131, respectively. As discussed above, these independent claims are patentable over the cited references. Therefore, new claims 171-178, which depend on independent claims 111, 114, 128 and 131, are also patentable.

CONCLUSION

In view of the above remarks, Applicants respectfully request that the Examiner reconsider pending claims 111-178 with a view towards allowance.

The Examiner is invited to call the undersigned attorney at (212) 326-3939 if a telephone call could help resolve any remaining issues.

Should any fees be required, please charge such fees to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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Enclosure